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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,295	07/12/2004	Ferdinando Giordano	26177	8153

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EXAMINER
MAIER, LEIGH C

ART UNIT	PAPER NUMBER
1623	

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07/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,295	GIORDANO ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-8 and 10-15 have been amended and are pending. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any objection or rejection not expressly repeated has been withdrawn.

Claim Rejections - 35 USC § 103

Claims 1, 3, 6-8 and 15 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Klokkers et al (WO 98/40069) as set forth in the previous Office action.

The product-by-process claim 1 has been amended to limit the species of pantoprazole and cyclodextrin derivatives used in the recited inclusion complex. The process by which the product is prepared has been amended to limit the solvent to one "consisting essentially of an aliphatic alcohol." However, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In the instant case, the product is an inclusion complex consisting of a pantoprazole compound and a cyclodextrin. The complex itself is limited to these entities, but it does not limit with what it may be combined. This is borne out by the recitation of dependent claims such as claim 8 that require the addition of a pharmaceutical auxiliary. As long as the pantoprazole:cyclodextrin inclusion complex is present, it does not appear to matter what else is present or absent.

Applicant's arguments filed March 21, 2007 have been fully considered but they are not persuasive.

Applicant argues that Klokkers is an inoperative reference because the Klokkers procedure does not produce an inclusion complex and cites the results reported in the specification. However, from the information in the specification, it does not appear that the Klokkers procedure was replicated exactly as taught. Specifically, Applicant uses a different wetting agent and omits the amino acid used in Klokkers. The reference teaches that the procedure produces an inclusion complex with omeprazole:cyclodextrin complex, and the examiner maintains that it would be obvious to modify this process to use pantoprazole because this is suggested in the reference.

Applicant further contends that Klokkers does not teach or suggest a 1:1 inclusion complex but rather teaches a 1:10 inclusion complex and a 1:2 inclusion complex. The examiner respectfully disagrees with this interpretation of the reference. The reference describes "a pharmaceutical formulation, wherein the molar ratio of omeprazole to cyclodextrin is 1 to 10 and preferably 1 to 2." This passage does not describe the actual inclusion complex that is formed. It describes the ratio in which the components are combined. For example, a compound may inherently form a 1:1 inclusion complex with a cyclodextrin, but it may be combined with a 10-molar excess of a cyclodextrin. The ratio of the inclusion complex formed would still be 1:1 even in the presence of an excess of cyclodextrin.

Applicant further argues that claim 1 recites "consisting of" transitional language, and claim 1 does not emcompass an amino acid. Klokkers describes the product as being a benzimidazole/cyclodextrin complex in the presence of an amino acid. The examiner does not

find that the product is described as being an inclusion complex wherein the cyclodextrin complexes with both the benzimidazole and amino acid simultaneously. As the examiner does not have facilities to prepare the product of the art, the burden in on the Applicant to demonstrate that said product is not embraced by the claims.

Claims 1-3, 6-8, 11, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klokkers et al (WO 98/40069) and Kohl (WO 00/10995).

Klokkers teaches as set forth previously. The reference does not teach the use of the particularly recited pantoprazole species.

Kohl teaches as set forth previously.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use any known salt form of the benzimidazole species, such as pantoprazole, for the preparation of cyclodextrin inclusion complexes with a reasonable expectation of success for their art-disclosed utility. The artisan would be motivated to use pantoprazole sodium sesquihydrate or pantoprazole magnesium dihydrate because Ishiguro had suggested the use of benzimidazole salts, and Kohl and taught their availability.

Claims 1, 3, 6-8, 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klokkers et al (WO 98/40069) and Min et al (WO 93/13138).

Klokkers teaches as set forth previously. The reference does not teach the full scope of cyclodextrins or the treatment of particular diseases or disorders.

Min teaches as set forth previously. The reference further teaches the use of benzimidazole compounds for the treatment of a variety of disorders. See page 1, lines 18-21.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare an inclusion complex consisting of pantoprazole with any of the cyclodextrins taught by Min. Klokkers had established the desirability of preparing these complexes and a functional equivalence between pantoprazole and the benzimidazole compounds disclosed by Min. Therefore, one of ordinary skill would reasonably expect success in preparing these complexes. It would be further obvious to use the complex for the treatment of the disorders taught by Min as being treatable by these benzimidazole compounds with a reasonable expectation of success.

Claims 1, 3-8, 10, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klokkers et al (WO 98/40069) and Min et al (WO 93/13138) in view of Ishiguro et al (WO 96/38175).

Klokkers teaches as set forth previously. The reference does not teach the preparation of the complex by reacting the complexing components in a solvent consisting essentially of an aliphatic alcohol, such as ethanol.

Ishiguro and Min teach as set forth previously.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method described by Ishiguro for the preparation of an inclusion complex of pantoprazole and any of the cyclodextrins taught by Klokkers and Min. In the absence of unexpected results, one of ordinary skill would reasonably expect success in using

any disclosed method for the preparation of cyclodextrin complexes to work generally with other cyclodextrins. It would be further obvious to administer these complexes for the treatment of disorders discussed by Min or Ishiguro.

The process claims have been amended to recite a method of preparing the inclusion complex comprising the reacting the components in a solvent consisting essentially of an aliphatic alcohol. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) However, absent a clear indication in the specification of claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See MPEP 2111.03 [R-3]. In the instant case, there is no exemplification of a process comprising an aliphatic alcohol in any form or an explanation of the basic and novel characteristics of a process using a solvent consisting essentially of said alcohol.

Claims 1-8 and 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klokkers et al (WO 98/40069) and Kohl (WO 00/10995) in view of Ishiguro et al (WO 96/38175).

Klokkers, Kohl and Ishiguro teach as set forth above.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method described by Ishiguro for the preparation of an inclusion complex of pantoprazole and any of the pantoprazole species taught by Klokkers and Kohl. In

the absence of unexpected results, one of ordinary skill would reasonably expect success in using any disclosed method for the preparation of cyclodextrin complexes to work generally with other cyclodextrins. It would be further obvious to administer these complexes for the treatment of disorders discussed by Ishiguro. See discussion of the "consisting essentially of" transitional phrase above.

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Monday, Tuesday and Thursday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Primary Examiner
June 11, 2007